HYLEE53.001AUS PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Yang, et al.	Group Art Unit 1638
Appl. No.	:	09/921,013	
Filed	:	July 27, 2001	
For	:	NOVEL MICROORGANISM ISOLATED FROM CHINESE ELM (ULMUS SP.) AND PROCESS FOR PREPARING EXOPOLYSACCHARIDES BY EMPLOYING THE MICROORGANISM	
Examiner	:	Vera Afanasyeva	

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as first-class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on 9/27/03 (Date)
Paul C. Stewart, Reg. No. 30,826

DECLARATION UNDER 37 C.F.R. § 1.132

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I, Young Joo Kim, do hereby declare as follows:

1. I received a Ph.D. in the Department of Chemical Engineering from Rensselaer Polytechnic Institute in 1993. Since 1995, I have been employed in Samsung Advanced Institute of Technology as a Senior Researcher in Kiheung, Korea. A list of my representative publication is attached hereto as Appendix A.

2. I have read the Official Action dated December 27, 2002 and the references cited therein. I respectfully disagree with the Examiner for the reasons set forth below.

3. Along with my co-inventor, I had the bacterial species first referred to as "BSID-805-1" (hereafter referred to as "the Species") submitted to the Korean Collection for Type

Cultures, which is associated with the Korea Research Institute of Bioscience and Biotechnology (hereafter "KRIBB"), an international depository authority, under accession (deposition) No. KCTC 0687BP on Nov. 3, 1999.

4. As part of their routine, scientists at KRIBB did a taxonomical study of the Species. The results of this study are attached as Appendix B (hereafter "the Study").

5. One part of the Study was a fatty acid analysis performed using the MIDI apparatus. The fatty acid analysis did not show a 100% match with any known bacterial Species. Indeed, the analysis showed that the Species was only 47% like *Enterobacter sakazakii*. The best match according to this analysis was to *Pseudomonas aeruginosa*.

6. A second part of the Study compared the Species to the metabolic pathway diagnostics of other known bacteria. The first of these two panels of metabolic pathway diagnostics (API 20 NE) will identify gram-negative non-*Enterobacteriaceae microorganisms*. This first panel showed that the Species had a 93.6% identity with *Aerobacter hydrophilia*. The second of the two panels (API 20 E) identifies species and sub-species of *Enterobacteriaceae* as well as group and species identification of non-fermenting gram-negative bacteria. This second panel found that the Species had a 99.7% likeness with *Enterobacter sakazakii*. It is useful to note that the Species did not react the same way with four of the twenty individual tests that form the second panel. As the results indicate, 100% of the *sakazakii* bacteria react with the nitrate reduction and oxidation (glucose) tests, while the Species did not react in either such test.

7. The Study also included a 16S ribosomal RNA analysis and comparison with other species. Based on this analysis, two phylogenetic trees were made to illustrate the relation between the Species and other bacteria that had the most similar RNA sequences. As can be seen on page 9 of the Study, the Species is not grouped together in a family with any other known bacteria.

8. Finally, the Study sets forth on page 10 sets forth a carbon source utilization analysis ("Biolog") for the Species. This analysis is not compared to carbon source utilization analysis of other bacteria.

9. Based on the Study, KRIBB decided that the Species was a novel Species of *Enterobacter*. We named the Species *Enterobacter sp.* SSYL (KCTC 0687BP).

10. My co-inventor and I also subjected the Species to a comparative carbon source utilization test using the Biolog instrument and standard methods. We compared *Enterobacter sakazakii* with the Species and found that for the panel of 96 individual tests in the Biolog analysis, the two organisms gave the opposite results in 11 of the tests. Also, there was some question that the two organisms gave the same results in 20 of the other individual tests. (The read-out for this Biolog test is attached as Appendix C).

11. My co-inventors and I also did a comparative 16S ribosomal RNA analysis on the Species and on the *Enterobacter sakazakii* as wells as on the *Enterobacter cloacae* organisms. (The results of these two analyses are attached as Appendix D and E, respectively). The test showed that the Species had 98% identity with the *Enterobacter sakazakii* microorganism and 94.5% identity with *Enterobacter cloacae* microorganism.

12. The apparent closeness in the 16S ribosomal RNA analysis can be misleading when taken out of context of a full range of taxonomical testing. For instance, a BLAST search of the NCBI database (attached as Appendix F) shows that the in a similar analysis organisms from different genera such as *Citrobacter* (Page 6), *Salmonella* (Page 11) and *Klebsiella* (page 13) have a 97% identity reading with *Enterobacter sakazakii*. Thus, microorganisms can be clearly distinct from one another and have a misleading high percentage of identity. The Species is clearly different from either *Enterobacter sakazakii* or *Enterobacter cloacae* as confirmed by the above tests.

13. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that

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these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,

Dated: May 26, 2003

By: _____
Young Joo Kim

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